

§ 884.3650

used to treat conditions such as uterine prolapse (falling down of uterus), uterine retroposition (backward displacement), or gynecologic hernia.

(b) *Classification.* Class II (performance standards).

§ 884.3650 Fallopian tube prosthesis.

(a) *Identification.* A fallopian tube prosthesis is a device designed to maintain the patency (openness) of the fallopian tube and is used after reconstructive surgery.

(b) *Classification.* Class II (performance standards).

§ 884.3900 Vaginal stent.

(a) *Identification.* A vaginal stent is a device used to enlarge the vagina by stretching, or to support the vagina and to hold a skin graft after reconstructive surgery.

(b) *Classification.* Class II (performance standards).

Subpart E—Obstetrical and Gynecological Surgical Devices

§ 884.4100 Endoscopic electrocautery and accessories.

(a) *Identification.* An endoscopic electrocautery is a device used to perform female sterilization under endoscopic observation. It is designed to coagulate fallopian tube tissue with a probe heated by low-voltage energy. This generic type of device may include the following accessories: electrical generators, probes, and electrical cables.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 884.3.

[45 FR 12684-12720, Feb. 26, 1980, as amended at 52 FR 17741, May 11, 1987]

§ 884.4120 Gynecologic electrocautery and accessories.

(a) *Identification.* A gynecologic electrocautery is a device designed to destroy tissue with high temperatures by tissue contact with an electrically heated probe. It is used to excise cervical lesions, perform biopsies, or treat chronic cervicitis under direct visual

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observation. This generic type of device may include the following accessories: an electrical generator, a probe, and electrical cables.

(b) *Classification.* Class II (performance standards).

§ 884.4150 Bipolar endoscopic coagulator-cutter and accessories.

(a) *Identification.* A bipolar endoscopic coagulator-cutter is a device used to perform female sterilization and other operative procedures under endoscopic observation. It destroys tissue with high temperatures by directing a high frequency electrical current through tissue between two electrical contacts of a probe. This generic type of device may include the following accessories: an electrical generator, probes, and electrical cables.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 884.3.

[45 FR 12684-12720, Feb. 26, 1980, as amended at 52 FR 17741, May 11, 1987]

§ 884.4160 Unipolar endoscopic coagulator-cutter and accessories.

(a) *Identification.* A unipolar endoscopic coagulator-cutter is a device designed to destroy tissue with high temperatures by directing a high frequency electrical current through the tissue between an energized probe and a grounding plate. It is used in female sterilization and in other operative procedures under endoscopic observation. This generic type of device may include the following accessories: an electrical generator, probes and electrical cables, and a patient grounding plate. This generic type of device does not include devices used to perform female sterilization under hysteroscopic observation.

(b) *Classification.* Class II (performance standards).

§ 884.4250 Expandable cervical dilator.

(a) *Identification.* An expandable cervical dilator is an instrument with two handles and two opposing blades used manually to dilate (stretch open) the cervical os.